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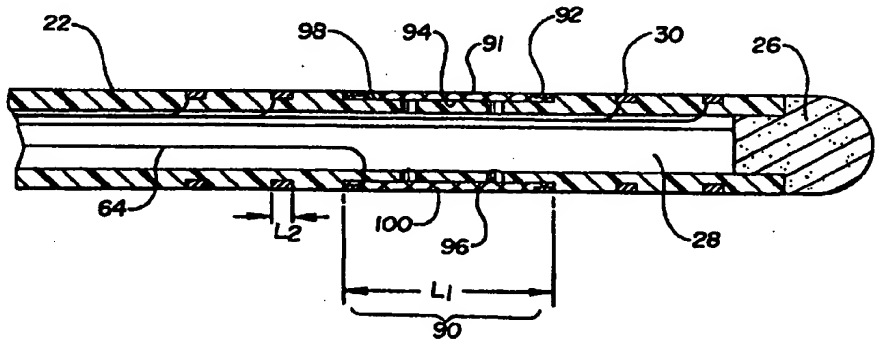

(57) Abstract

The invention relates to an ablation catheter (20) which controls the temperature and reduces the coagulation of biological fluids on a tip (26) of a catheter (20); prevents the impedance rise of tissue in contact with the catheter tip (26); and maximizes the energy transfer to the tissue, thereby allowing an increase in the lesion size produced by the ablation. The ablation catheter includes a tip (26) for applying electrical energy to biological tissue. Passages (48) are positioned within the tip (26) in a variety of manners for directing a fluid flow through the tip (26) to the exterior surface of the tip (26) to control the temperature and form a protective fluid layer around the tip (26). Monitoring structure (47) is also positioned within the tip for measurement of the electrical potentials in a biological tissue. Ablation electrode structure (30) is also positioned within the tip (26) for application of ablative energy to the biological tissue. A flexible, extended embodiment electrode (90) provides the capability to form deep, linear lesions along a portion of a heart wall during ablation for the treatment of particular arrhythmias.

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FLUID COOLED AND PERFUSED TIP FOR A CATHETER

Field of the Invention

The invention relates to a flexible, fluid perfused elongated electrode for an ablation catheter to form linear lesions in tissue.

Background of the Invention

The pumping action of the heart is controlled in an orderly manner by electrical stimulation of myocardial tissue. Stimulation of this tissue in the various regions of the heart is controlled by a series of conduction pathways contained within the myocardial tissue. The impulse to stimulate is started at the sino-atrial (SA) node and is transmitted through the atria. The signals arrive at the atrio-ventricular (AV) node which is at the junction of the atria and ventricles. The signal passes through the AV

node into the bundle of HIS, through the Purkinje fiber system and finally activates the ventricular muscle. At the completion of ventricular stimulation, heart tissue rests to allow the cells to recover for the next stimulation. The stimulation is at the cellular level, and is a changing of the polarity of the cells from positive to negative.

Cardiac arrhythmias arise when the pattern of the heartbeat is changed by abnormal impulse initiation or conduction in the myocardial tissue. The term tachycardia is used to describe an excessively rapid heartbeat resulting from repetitive stimulation of the heart muscle. Such disturbances often arise from additional conduction pathways which are present within the heart either from a congenital developmental abnormality or an acquired abnormality which changes the structure of the cardiac tissue, such as a myocardial infarction.

One of the ways to treat such disturbances is to identify the conductive pathways and to sever part of this pathway by destroying these cells which make up a portion of the pathway. Traditionally, this has been done by either cutting the pathway surgically, freezing the tissue, thus destroying the cellular membranes, or by heating the cells, thus denaturing the cellular proteins. The resulting destruction of the cells eliminates their electrical conductivity, thus destroying, or ablating, a certain portion of the pathway. By eliminating a portion of the pathway, the pathway no longer conducts and the tachycardia ceases.

One of the most common ways to destroy tissue by heating has been the use of either electromagnetic energy or light. Typically, sources such as

radiofrequency (RF), microwave, ultrasound, and laser energy have been used. With radiofrequency energy, a catheter with a conductive inner core and a metallic tip are placed in contact with the myocardium and a circuit is completed with a patch placed on the patient's body behind the heart. The catheter is coupled to a radiofrequency generator such that application of electrical energy creates localized heating in the tissue adjacent to the distal (emitting) electrode.

Due of the nature of radiofrequency energy, both the metallic tip and the tissue are heated simultaneously. The peak tissue temperatures during catheter delivered application of RF energy to myocardium occur close to the endocardial surface, such that the lesion size produced is approximately limited by the thermodynamics of radial heat spread from the tip. The amount of heating which occurs is dependent on the area of contact between the electrode and the tissue and the impedance between the electrode and the tissue. The higher the impedance, the lower the amount of energy transferred into the tissue.

Traditional electrode configurations have a small cylindrical metal tip electrode with one or more thin ring electrodes near the tip either to aid with ablation or to measure the impedance in nearby heart tissue. The size of the electrodes is limited because the catheter must remain flexible enough for the distal end of the catheter to be passed through the cardiovascular system into the heart. Solid metal electrodes limit the flexibility of the catheter. These electrodes form a circular lesion at the point of contact on the surface of the heart tissue. The cross section of the

lesion within the heart tissue is ellipsoidal in shape. These lesions are most effective in the treatment of accessory pathways, AV node re-entrant tachycardias and some forms of idiopathic ventricular tachycardia.

However, the treatment of a broader range of arrhythmias, such as atrial fibrillation and atrial flutter, may require linear lesions. An appropriate linear lesion would form a line on the surface of the heart and penetrate the full thickness of the heart wall. With traditional tip electrodes described above, the only way to form such a linear lesion would be to move the catheter during ablation to create a contiguous line from the discrete circular lesions. While this is theoretically possible, it is not practical to form such a line from the circular lesions because there are no visual markers that would allow the positioning of one lesion with respect to another lesion. Generally, the lesions are not visible under fluoroscopy.

One of the major problems with radiofrequency energy is the coagulation of blood onto the tip of the catheter, creating a higher impedance or resistance to passage of electrical energy into the tissue. As the impedance increases, more energy is passed through the portion of the tip without coagulation, creating even higher local temperatures and further increasing coagulum formation and the impedance. Eventually, enough blood is coagulated on the tip so that no energy passes into the tissue. The catheter must then be removed from the vascular system, the tip area cleaned and the catheter repositioned within the heart at the desired location. This process is not only time consuming, but it is also

difficult to return with precision to the previous ablation site because of the reduced electrical activity in the regions which have been previously ablated. Use of temperature sensors in the tip to modulate the power input to keep the electrode below the coagulation temperature of blood have been used. These systems inherently limit the amount of power which can be applied. Others have used closed loop cooling systems to introduce water into the tip, but these systems are larger than necessary because the coolant must be removed from the catheter.

In some research, an increase of impedance was noted in radiofrequency (RF) ablation at power levels above 7 watts (W) due to the formation of a thin insulating layer of blood degradation products on the electrode surface. Wittkampf, F. H. et al., Radiofrequency Ablation with a Cooled Porous Electrode Catheter , Abstract, JACC, Vol. 11, No. 2, Page 17A (1988). Wittkampf utilized an open lumen system at the distal electrode which had several holes perpendicular to the central lumen which could be cooled by saline. Use of the saline kept the temperature of the electrode at a temperature low enough so that the blood products would not coagulate onto the tip of the electrode.

Impedance rise associated with coagulum formation during RF catheter ablation was also noticed by Huang et al., Increase in the Lesion Size and Decrease in the Impedance Rise With a Saline Infusion Electrode Catheter for Radiofrequency Catheter Ablation, Abstract, Circulation, Vol. 80, No. 4, page II-324 (1989). A quadropolar saline infusion intraluminal electrode catheter was used to deliver RF energy at different levels.

The drawbacks of the existing catheter electrodes are that they do not minimize the contact of biological material with the tip of the catheter along with the cooling of the tissue in the vicinity of the tip. While cooling will help to reduce coagulation of blood and tissue onto the catheter, the continued contact of the biological material with the tip will result in further coagulation on the tip. This results in an increased electrical resistance and a further increase in local heating near the tip. Another difficulty with existing catheter electrodes is that the lesions are limited in size and shape. It is only with great difficulty that such electrodes can be used to form appropriate lesions for many cardiac arrhythmias.

Summary of the Invention

The invention relates to a catheter tip for cardiac signal measurement and monitoring, including a tip structure which is positioned at the end of the catheter. Path means are formed within the tip structure for directing a fluid from the interior of the tip structure to portions of the tip structure exterior surface, thereby providing a fluid protective layer surrounding the tip structure. Monitoring means are also included within the catheter tip structure for measurement of electrical potentials in a biological tissue.

The invention also relates to an ablation catheter which reduces the coagulation of biological fluids on a tip of a catheter, regulates the impedance rise of tissue in contact with the catheter tip, and maximizes the potential energy transfer to the tissue, producing a larger size lesion.

The ablation catheter includes a catheter body. The ablation catheter also includes a tip for monitoring electrical potentials, and applying electrical energy to a biological tissue. A fluid source is positioned at one end of the catheter for supplying a fluid flow through the catheter to the tip means. Passages are formed within the tip for directing the fluid flow through the tip means to the exterior surface of the tip means to form a protective fluid layer around the tip. Monitoring means are also positioned within the tip structure for measurement of the electrical potentials in a biological tissue. Ablation means are also positioned within the tip means for application of ablative energy to the biological tissue.

The invention also relates to an extended ablation catheter electrode that can produce a linear shaped lesion without moving the catheter from an initial position. The elongated electrode is preferably made from a fine metal mesh in electrical contact with the catheter handle. Construction of the extended electrode from the metal mesh allows the extended electrode to be sufficiently flexible that the extended electrode can be positioned within the heart. The inner surface of the mesh is in fluid communication with path means that directs fluid from the interior of the catheter through the mesh to form a protective fluid layer over the outer surface of the extended electrode.

Description of the Drawings

Figure 1 is a side elevational view of an ablation catheter and tip.

Figure 2 is a fragmentary enlarged section view of the catheter tip having a bulbous configuration.

Figure 3 is a fragmentary enlarged section view of the catheter tip having a spherical configuration.

Figure 4 is a fragmentary enlarged section view of a catheter tip having an extended rectangular shape.

Figure 5 is a fragmentary enlarged section view of a catheter tip having a rectangular shape showing the electrical conduit.

Figure 6 is a fragmentary enlarged section view of a solid catheter tip having a multiplicity of discrete fluid flow passages.

Figure 7 is a fragmentary enlarged section view of a solid catheter tip having a passage extending the length of the catheter tip.

Figure 8 is a cross section view of the catheter tip showing axial channels extending the length of the catheter tip.

Figure 9 is a cross section view of the catheter tip showing a multiplicity of radially directed channels encircling the catheter tip.

Figure 10 is a fragmentary enlarged section view of a catheter tip made of a ceramic insulating material having monitoring members.

Figure 11 is a fragmentary enlarged section view of a catheter having ring electrodes which have path means.

Figure 12 is a fragmentary enlarged section view of an alternative embodiment of a catheter having a large central lumen and a smaller lumen.

Figure 13 is a cross section view taken along line 13-13 of Figure 12.

Figure 14 is an enlarged fragmentary sectional view of a portion of the catheter tip and ring electrodes shown in Figures 2-5, 10, and 11.

Figure 15 is an enlarged fragmentary side perspective view of a catheter tip with an elongated flexible electrode, a tip electrode and several ring electrodes.

Figure 16 is a fragmentary enlarged section view of a catheter tip with an extended flexible electrode, a tip electrode and several ring electrodes.

These figures, which are idealized, are not to scale and are intended to be merely illustrative and non-limiting.

Detailed Description of the Invention

The invention relates to a catheter having a fluid perfused or insulated tip. Fluid passes through the tip structure, forming a fluid protective layer around the exterior surface of the tip structure. The fluid which permeates and surrounds the tip structure minimizes the amount of the biological material which comes in contact with the catheter tip structure, as well as cools the tip structure. The cooling fluid prevents a rise in the resistance (impedance) of the tissue to energy transfer from an ablation energy source, and maximizes the potential energy transfer to the tissue in communication with the catheter tip. As a result, a larger lesion size in the tissue is produced.

Referring to Figure 1, a side elevational view of catheter 20 is shown having catheter body 22, a handle 24, and a tip structure 26. Catheter body 22 may be of varying lengths, the length being determined by the application for catheter 20. Catheter body 22 is preferably made of a flexible, durable material, including, for example, thermoplastics such as

nylon, in which a braiding is embedded. Preferably, catheter body 22 includes a large central lumen 28, such as a three French (F) lumen in a four F to twelve F, preferably eight F catheter 20. Catheter body 22 may contain a plurality of ring electrodes 30 which surround the exterior surface of catheter body 22 at selected distances from the distal end 32 proximate tip structure 26.

As shown in Figure 1, handle 24 is positioned on the proximal end 34 of catheter body 22. Handle 24 may contain multiple ports, such as ports 36, 38. Port 36 may be utilized, in this embodiment, for electrical connections between electrophysiological monitoring equipment and electrical potential sites of the tissue. Electrical connection means 40, exiting through port 36, is positioned between and connects tip structure 26 and the electrophysiological monitoring equipment. Port 36 is in communication with central lumen 28 of catheter body 22 and may also be used for the introduction and passage of devices 42 through catheter 20. Port 38, in this embodiment, is connected to a fluid source and is also in fluid communication with central lumen 28 of catheter 20. Port 38 may be used for the entry of a fluid into catheter 20. Additional ports may be included on handle 24 which are in communication with central lumen 28. Port 36 may, for example, contain electrical connection means 40, and an additional port may contain device 42.

Referring to Figure 1, tip structure 26 is located at the distal end 32 of catheter body 22. Tip structure 26 may range from four (4) to twelve (12) French catheter tips. Tip structure 26 includes at least one attachable

electrode useful for monitoring electrical potentials of the tissue, measuring cardiac signals, and mapping to locate the tissue to be ablated. In addition, the tip structure may include monitoring means for measuring, monitoring, and adjusting the rate of fluid flow through tip 26 relative to biological parameters, such as tip and tissue temperature.

As shown in Figures 2-5, the overall shape of tip structure 26 may have a variety of configurations. The various configurations may be machined into the material comprising tip structure 26. Preferably, the shape of tip structure 26 permits catheter 20 to proceed readily through the vein or artery into which catheter 20 may be inserted. The shape of tip structure 26 is determined by the application for which catheter 20 is designed. For example, Figure 2 is a fragmentary enlarged section view of tip structure 26 having wall portions 27 which extend beyond the diameter D of catheter portions proximal to the tip. For example, a bulbous or dumbbell configuration, as shown in Figure 2, may be useful in situations requiring access to pathway ablations which lie on top of a valve or other relatively inaccessible site. Figure 3 illustrates a fragmentary enlarged section view of tip structure 26 which has a spherical or rounded configuration which may be advantageous, for example, in situations involving cardiac pathways underneath a valve. Figure 4 and Figure 5 illustrate fragmentary enlarged section views of tip structure 26 which vary in the length of tip structure 26. Tip structure 26 shown in Figure 4 may be useful in applications which lie along the myocardial wall, and tip structure 26 illustrated in Figure 5 may be particularly advantageous for

uses such as electrophysiological mapping.

Tip structure 26 may comprise a variety of materials. Preferably, the material used for tip structure 26 in the different embodiments includes a plurality of apertures or path means which are either randomly or discretely formed in or spaced throughout tip structure 26. The diameter of the apertures or path means is substantially smaller than the overall diameter of tip structure 26. The diameter dimensions of the path means in the different embodiments discussed below may vary, and may include microporous structures.

As illustrated in Figures 2-5, tip structure 26 is preferably made of a sintered metal which contains a plurality of randomly formed through-passages or path means 48 in tip structure 26. Generally, to create the sintered metal for tip structure 26, spherical particles, such as finely pulverized metal powders, are mixed with alloying elements. This blend is subjected to pressure under high temperature conditions in a controlled reducing atmosphere to a temperature near the melting point of the base metal to sinter the blend. During sintering (heating), metallurgical bonds are formed between the particles within the blend at the point of contact. The interstitial spaces between the points of contact are preserved and provide path means for fluid flow.

Paths means 48 in tip structure 26 comprise interstitial spaces forming structures which are randomly positioned, are of varying sizes, and are interconnected in a random manner with other interstitial spaces in tip structure 26 to provide fluid communication between central lumen

28 of catheter 20 and the exterior surface 50 of tip structure 26. Path means 48 are generally five to twenty microns in diameter, although this may vary. The metal material utilized for tip structure 26 should conduct heat well, have the ability to monitor electrical potentials from a tissue, and be economical to fabricate, such as stainless steel or platinum.

Alternatively, as shown in Figure 6, tip structure 26 may comprise a solid metal material. Figure 6 is a fragmentary enlarged section view of catheter body 22 connected to tip structure 26. Tip structure 26 in this embodiment comprises a solid metal, such as stainless steel or platinum, having a multiplicity of specifically formed apertures or path means 52 within tip structure 26 which provide fluid communication between central lumen 28 of catheter 20 and the exterior surface 50 of tip structure 26 for the passage of a fluid. The configuration of path means 52 is designed to provide a continuous layer of fluid over the exterior surface 50 of tip structure 26. Preferably, the apertures of path means 52 have a diameter less than five hundred microns, although this may vary. The metal material utilized for tip structure 26 shown in Figure 6 should conduct heat, as well as have the ability to monitor electrical potentials from a tissue.

Figure 7 is a fragmentary enlarged section view illustrating catheter body 22 attached to tip structure 26. Tip structure 26, in this embodiment, is preferably made of a solid metal material which conducts heat well, and has the ability to monitor and measure electrical potentials of a tissue, such as stainless steel or platinum. Alternatively, tip structure 26 may

comprise a dense ceramic material. As shown in Figure 7, a single orifice, channel or through path means 54 is formed through the length L of tip structure 26. Path means 54 is in fluid communication with central lumen 28 of catheter 20. Preferably, the aperture of path means 54 has a diameter less than five hundred microns, although this may vary.

Figures 8 and 9 illustrate alternative cross section embodiments of tip structure 26. Figure 8 illustrates tip structure 26 having a plurality of grooves or directional channels 56 which extend in an axial direction along the length L of tip structure 26. Interconnecting channels may extend radially between channels 56 to aid in the fluid distribution over tip structure 26. Figure 9 illustrates a plurality of annular grooves or directional channels 58 which encircle tip structure 26 in a radial manner. As shown in Figure 9, channels 60 extend between path means 54 and channels 58 to direct the fluid flow through central lumen 28 and path means 54 to the exterior surface 50 of tip structure 26. In these embodiments, channels 56, 58 are designed to communicate with path means 54 to provide a continuous, evenly distributed fluid protective layer over substantially the entire exterior surface 50 of metallic tip structure 26.

Referring to Figure 10, an alternative embodiment of tip structure 26 is shown. Figure 10 is a fragmentary enlarged section view of catheter body 22 attached to tip structure 26. Tip structure 26, in this embodiment, preferably comprises a ceramic insulating material which includes randomly formed path means 61. Path means 61 are generally five to twenty microns in diameter, although this may vary. Path means 61 are in

fluid communication with central lumen 28 of catheter 20. In addition, tip 26 includes at least one monitoring member 62 positioned throughout tip structure 26. Member(s) 62 may be of varying shapes and dimensions. Preferably, members 62 are made of a conductive material suitable for monitoring electrical activity and for application of electrical energy to a biological tissue, such as stainless steel or platinum. Tip structure 26, in this embodiment, may contain axial or radial directional channels on exterior surface 50 of tip structure 26.

As shown in Figures 1 and 11, ring electrodes 30 may be attached to catheter body 22. Ring electrodes 30 are connected to the monitoring equipment by electrical connection means 64 through port 36 in handle 24. Electrical connection means 64 are attached to ring electrodes 30, by, for example, soldering or other suitable mechanical means. Ring electrodes 30 may be made of a material which has path means similar to path means 48, 52, 60 as described above with reference to tip structure 26 in Figures 2-5 and 10, and is preferably a sintered metal material. A plurality of ring electrodes 30 may be positioned at distal end 32 of catheter 20. Ring electrodes 30 may be used for electrophysiological monitoring and mapping, as well as for ablation. Fluid passes from central lumen 28 through path means in ring electrodes 30 to form a fluid protective layer around the exterior surface 66 of ring electrodes 30. In a more flexible embodiment, ring electrodes 30 may be separated by flexible plastic material forming portions of catheter body 22. The electrodes may be spaced at various distances, but in a flexible arrangement may be about 1

mm to 2 mm apart.

Figure 12 and Figure 13 illustrate another embodiment of catheter 20. A central lumen 74 extends the length of catheter 20. Distal end 76 of catheter 20 may include a smaller diameter lumen 78 relative to lumen 74 positioned substantially parallel and adjacent to central lumen 74. Lumen 74 permits the introduction of a device, such as described above regarding device 42, through the center of catheter 20, as well as the passage of the fluid. Lumen 78 may be connected to port 38, and may also be used to direct the fluid to tip structure 26, such that the fluid passes through path means 48, 52, 54, 61 in tip structure 26, as discussed above in relation to Figures 2-10. Non-permeable layer 82, such as a plastic liner layer, may be positioned between lumen 74 and lumen 78 to ensure that the fluid in lumen 78 is directed through passages or path means 48, 52, 54, 61 in tip structure 26 to the exterior surface 50 of tip structure 26. Ring electrodes may also be used in this embodiment to direct fluid to the exterior surface of tip structure 26 and catheter 20 to form the continuous and evenly distributed fluid protective layer 83 over substantially the entire exterior surface of the tip structure.

Figure 14 illustrates an enlarged fragmentary section view of a portion of catheter tip structure 26 and/or ring electrodes 30 shown in Figures 2-5, 10, and 11. Substantially spherical particles 84, preferably biologically compatible metal particles, are positioned and arranged so as to form and create numerous interconnected, omnidirectional, tortuous path means 48, 52, and 61 (only 48 shown) through tip structure 26. Fluid flows

through these tortuous path means 48, 52, 61 in the varied tip structure configurations to the exterior surface 50 of tip structure 26 or exterior surface 66 of ring electrodes 30 to uniformly and evenly distribute the fluid around tip structure 26. Substantially all path means 48, 52, 61 at surface 50 of tip structure 26 or surface 66 of ring electrodes 30 are in fluid communication with central lumen 28.

A flexible embodiment specifically designed to produce linear lesions is shown schematically in Figures 15 and 16. The elongated electrode 90 is preferably constructed from a porous or microporous mesh 91 woven from small diameter metallic threads or merely configured with an appearance of a fine weave. The porous mesh can also be constructed from a series of small porous metal rings closely spaced to each other. Preferably, the microporous mesh 91 covers an entire circumference near the distal end 32 of the ablation catheter. End portions of the mesh 91 are securely connected to the shaft through mechanical clamps, connectors or adhesive bonds 92.

The elongated electrode 90 is electrically connected to the handle 24, shown in Figure 1, through electrical connection means 64 preferably comprising at least one conducting wire attached to the electrical interface connection 40 at handle 24. For ablation, appropriate electrical current is supplied to elongated electrode 90 through electrical connection means 64. The electrical current can be direct current or alternating current, and preferably is a radiofrequency signal. A flexible, extended embodiment electrode provides the capability to form deep, linear lesions along a

portion of a heart wall during ablation for the treatment of particular arrhythmias. The fluid insulating/protecting character of the invention is more important as the electrode length increases due to the corresponding increase in possible localized uneven heating along the length of the electrode. Such uneven heating leads to the formation of hot spots which result in biological tissue coagulation. However, creation of this continuous fluid protective layer reduces the possibility of areas of coagulation by maintaining a more even temperature and, when using conductive saline, creation of a conductive gap-filler material (the saline) to provide more uniform electrical distribution of energy.

The inside surface 94 of the elongated electrode 90 is exposed to the central lumen 28 via a plurality of macroscopic holes 96. Holes 96 are preferably sized between about 0.1 millimeters (mm) to about 3 mm, and preferably about 0.2 mm to about 1.0 mm. Fluid flows from the proximal end 34 of the catheter down a fluid interface in the central lumen 28 to macroscopic holes 96. The pressure of the fluid within the central lumen 28 forces water to disperse in the annular space 98 between the shaft of the catheter and the fine weave forming the mesh 91. The porosity of the mesh 91 is selected such that the resistance to the flow of fluid through the mesh 91 is significantly larger than the flow resistance at interconnecting holes 96. This selection of porosity of the mesh 91 ensures that there is an essentially even flow of fluid over the outer surface 100 of the elongated electrode 90.

Generally, the length L_1 of elongated electrode 90 is significantly

larger than the length L_2 of the ring electrodes 30. The length of elongated electrode 90 is selected to produce the size of the linear lesion appropriate for the treatment of the patient. This length will preferably range from about 5 mm to about 5 centimeters (cm). This length will often more preferably range from about 0.5 cm to about 1.5 cm.

A ring electrode 30 could not be constructed with a width contemplated for the elongated electrode 90 because the ring electrode 30 would be too rigid. The elongated electrode 90 is flexible similar to or even more than the catheter body 22. This flexibility allows the elongated electrode 90 to have the appropriate width without limiting the capability of passing the distal end 32 of the catheter conveniently through the cardiovascular system into the heart.

The fluid introduced through ports 38, macroscopic holes 96 or other orifices, of catheter 20 is preferably a biologically compatible fluid, and may be in a gaseous or liquid state. For example, the fluid may comprise carbon dioxide, nitrogen, helium, water, and/or saline. Fluid enters through, for example, port 38 and is passed though central lumen 28 of catheter body 22. The fluid perfuses tip structure 26 and/or ring electrodes 30 through the path means in tip structure 26 and/or ring electrodes 30, and creates a fluid protective layer surrounding exterior surfaces of tip structure 26 or exterior surfaces of electrodes 30, 90 thereby minimizing contact of tip structure 26 or electrodes 30, 90 with biological material, such as blood.

The rate of fluid flow through central lumen 28 of catheter 20 may

vary and range from 0.1 ml/min. to 40 ml/min. Fluid flow through catheter 20 may be adjusted by a fluid infusion pump, if the fluid is liquid, or by pressure, if the fluid is a gas. The fluid flow is regulated by the infusion pump for the liquid fluid, or by a needle valve if a gas, so as to maintain an optimal disbursing flow over the tip structure 26 and/or electrodes 30, 90 and maintain a desired tip temperature. Preferably, the protective layer of fluid covers all or substantially all of the surface area of tip structure 26 and is between about 0.001 mm and 1 mm, and more preferably, about 0.01 mm. in thickness, although this may vary depending on the application, and may vary in thickness during a given procedure.

Temperature sensing means 47 (for example as shown in Figures 3 and 4) may be incorporated into tip structure 26 for sensing and measuring the temperature of tip structure 26 and for sensing and measuring the temperature of the biological tissue in contact with tip structure 26. Temperature sensing means 47 may be incorporated in any of the tip structure embodiments shown in Figures 2-10, 15-16. The temperature sensing means generally comprises at least one temperature sensor, such as a thermocouple or thermistor. In addition, temperature sensing means 47 may be utilized as a feedback system to adjust the flow rate of the biologically compatible fluid to maintain the temperature of the tip structure at a particular temperature within a designated range of temperatures, such as 40°C to 95°C. Also, temperature sensing means 47 may be used as a feedback system to adjust the flow rate of the biologically compatible fluid so as to maintain the temperature of the biological tissue

in contact with tip structure 26 at a particular temperature within a designated range of temperatures, such as 40°C to 95°C. The temperature of the tissue or tip structure 26 is controlled by the temperature of the fluid, the distribution of the fluid relative to internal and external surfaces to the tip structure, the energy applied to the catheter, and the fluid flow rate.

Catheter 20 may include ablation means within tip structure 26. Preferably, the ablation means may be a wire connected to an RF energy source, although other types of electrical energy, including microwave and direct current, or ultrasound may be utilized. Alternatively, the ablation means may include optical fibers for delivery of laser energy. The ablation means may be connected to an energy source through port 36, or an additional port.

As shown in Figure 1, device 42 may be passed through central lumen 28 of catheter 20. Device 42 may include, for example, a guidewire for ease of entry of catheter 20 into the heart or vascular system; a diagnostic device, such as an optical pressure sensor; a suction catheter for biopsy of biological material near the distal tip; an endoscope for direct viewing of the biological material in the vicinity of the distal tip of the catheter; or other devices.

In one example of operation, catheter body 22 of catheter 20 is preferably percutaneously inserted into the body. The catheter is positioned so that it lies against cardiac tissue such that the flexible porous elongated electrode 90 makes contact along its length with the tissue area

that is to be ablated. Along the line of contact, energy will flow from the conductive source to the electrode and into the cardiac tissue. Simultaneous fluid flow is maintained around the electrode creating a buffer between the tissue and the electrode. Tip structure 26, as an electrode, may also be utilized to measure electrical potentials of the tissue and provide information regarding cardiac signal measurement. Electrical connection means 40 extends from tip structure 26, through port 36, and is connected to monitoring equipment. Tip structure 26 may be utilized to map, monitor, and measure the cardiac signals and electrical potentials of the tissue, and locate arrhthymogenic sites.

A biologically compatible fluid is introduced through port 38. The fluid passes through a central lumen of catheter body 22 and is directed to tip structure 26. The fluid passes through tip structure 26 and/or ring electrodes 30 and/or elongated electrode 90 through path means 48, 52, 54, 61 or holes 96 in a manner determined by the embodiment of distal end 32 used. The fluid perfuses tip structure 26 and forms a fluid protective layer around exterior surface 50 of tip structure 26 and/or exterior surface 66 of ring electrodes 30 and/or the exterior surface of the elongated electrode 90. The fluid layer formed around catheter tip structure 26 and/or ring electrodes 30 and/or elongated electrode 90 maintains biological materials, such as blood, at a distance from catheter tip structure 26, thereby minimizing contact of catheter tip structure 26 with the biological material, as well as cooling tip structure 26 and/or elongated electrode 90. Since there is a consistent, controlled buffer layer between the biological

material and catheter tip structure 26 and/or the elongated electrode 90, the coagulation of biological materials is reduced and the impedance or resistance to energy transfer of the tissue near the distal end 32 of the catheter 20 is regulated and minimized during ablation.

Once the site has been located by the monitoring of the electrophysiological signals of the tissue, the ablative energy is activated. As a result of the fluid protective layer, the transfer of electrical energy to the tissue is enhanced. Increased destruction of cardiac tissue also results from tip structure cooling since larger and deeper lesions in the cardiac tissue are achieved than have been previously possible. Use of the elongated electrode 90 allows the production of deep linear lesions.

The flow rate of the fluid over exterior surface 50 of tip structure 26 or exterior surface 66 of ring electrodes 30 or exterior surface of elongated electrode 90 may be accomplished in a controlled manner so that a thin fluid film is formed around exterior surface 50, 66, 100 of tip structure 26, ring electrodes 30 and elongated electrode 90. The maintenance of a controlled, stable, uniform fluid film along substantially the entire exterior surface of tip 26, ring electrodes 30 and elongated electrode 90 may be accomplished by using the various embodiments of distal end 32 described above having a multiplicity of passages or path means 48, 52, 54, 61 or holes 96. Path means 48, 52, 54, 61 and holes 96 permit an even, consistent distribution of minute quantities of a biologically compatible fluid over substantially the entire tip exterior surface 50 or ring electrodes exterior surface 66.

The fluid can be pumped through tip structure 26, or heat generated by the electrical or ablation process can be used to expand the fluid and create a movement of fluid to the exterior surface 50, 66 of tip structure 26 or ring electrodes 30 or elongated electrode 90. This movement of fluid provides a buffer or protective insulating layer between the exterior surface of tip structure 26 and/or ring electrode 30 and/or elongated electrode 90 and the biological material, such as blood, thereby reducing the coagulation of biological materials on tip structure 26 and/or ring electrode 30 and/or elongated electrode 90. In addition, the movement of fluid over and around tip structure 26 may be aided by passages or channels 56, 58 on exterior surface 50 of tip structure 26. Cooling of tip structure 26 and/or ring electrode 30 and/or elongated electrode 90 increases the lesion size produced by the ablation means since the point of maximum tissue temperature is likely moved away from tip structure 26, which allows for an altered tissue heat profile, as further described below.

Another advantage of the fluid layer buffering the surface area of tip structure 26 and/or ring electrodes 30 and/or elongated electrode 90 is that the fluid layer also cools the tissue adjacent tip structure 26 and elongated electrode 90 during ablation. In addition, the fluid aids in maintaining the tissue adjacent tip structure 26 and elongated electrode 90 in a cooler and potentially more conductive state, which permits more electricity or ablative energy to enter the tissue. As a result, larger lesions are produced because a larger voltage can be applied, producing a larger electric field without producing excessive temperatures and coagulum formation at the

tip/tissue interface. Lesions are produced with this invention in the form of a line measuring about 1 cm to about 4 cm in length and about 3 mm to about 5 mm in width while simultaneously maintaining the fluid protective layer. This is accomplished without having to move the catheter and without requiring several ablations. Also, the greater the pressure of the fluid, the more biological products are kept from the field of influence of, or area surrounding, tip structure 26 and/or elongated electrode 90.

A control system may be included for controlling and regulating the electrical potentials and temperatures in a manner that allows for determination of the ablation effects in the tissue. It is possible to control the distribution of tissue heating by controlling the temperature of tip structure 26 and/or elongated electrode 90 and the radiofrequency voltage, or other energy used, applied between tip structure 26 and/or elongated electrode 90 and a reference electrode on the surface of the body. The voltage may be set to achieve a desired electrical field strength, and the temperature of tip structure 26 and/or elongated electrode 90 may be set to provide a desired temperature distribution of the tissue. The temperature distribution will then determine the size of the lesion, i.e., the denatured protein dimensions in the myocardium.

The fluid flow rate can be regulated relative to biological parameters, such as tissue temperature, by the temperature sensing means. For instance, if the temperature of the tissue increases, the fluid flow rate can be increased by the regulation of the fluid infusion pump or gas needle

valve. If the tissue temperature adjacent tip structure 26 and/or elongated electrode 90 is not high enough, the fluid flow rate can be decreased. This permits power to be set independently of temperature. It is significant to note that it is normally not necessary to remove the introduced fluid from the body.

It is also possible to generate reversible affects of ablation by use of a cooling fluid down the central lumen 28 of catheter 20 and tip structure 26, or by use of a low temperature controlled or elevational heating. An area in the heart tissue is quenched with a cold or icy fluid to produce a tissue temperature of 0°C to 30°C, or heated with electrical energy with closed loop temperature controls as described above to produce tissue temperatures ranging from 40°C to 48°C. Those cool and warm temperatures slow the conduction of signals and temporarily and reversibly eliminate the conduction pathways. This technique may be advantageously used to see the affect on the tissue before the tissue is permanently affected. The heart tissue gradually heats or cools back to normal. This technique is also advantageous since no catheter exchange would be required.

Various modifications and alterations of this invention will become apparent to those skilled in the art without departing from the scope and spirit of this invention.

What is claimed:

1. A catheter tip for ablation of tissue comprising:

a) an elongate shaft having shaft walls defining a shaft inner lumen and shaft wall outer surfaces, the shaft having a proximal attachment end portion and a distal tip portion;

b) an electrode portion comprised of porous metal having portions mechanically connected to said shaft and electrically connected to a conductor within said shaft, said electrode placed circumferentially around a portion of said shaft and having an inner surface facing toward said shaft and an outer surface facing away from said shaft; and

c) shaft wall structures defining fluid flow apertures extending from the shaft inner lumen to the shaft wall outer surfaces; the apertures allowing the flow of fluid from the shaft inner lumen to the porous metal electrode inner surface, and the porous metal electrode defining fluid flow apertures suitable for the flow of said fluid through the fluid flow apertures to create a protective layer of fluid around the electrode outer surface.

2. The catheter tip of claim 1 in which the porous metal electrode comprises a sintered metal material.

3. The catheter tip of claim 1 further comprising solid ring electrodes around said shaft near said porous metal electrode, said solid ring electrodes having an electrical connection to a conductor within said shaft.

4. The catheter tip of claim 1 further comprising a tip electrode at said distal tip of said shaft, said tip electrode having an electrical connection to a conductor within said shaft.

5. The catheter tip of claim 1 in which the electrode portion comprises porous metal ring electrodes separated by flexible plastic shaft wall segments.

6. The catheter tip of claim 1 in which the porous metal electrode portion comprises an elongated flexible woven mesh metal structure.

7. The catheter tip of claim 1 further comprising temperature sensing means used as a feedback system for adjusting the flow rate of a fluid through the catheter tip.

8. The catheter tip of claim 1 further comprising ablation means.

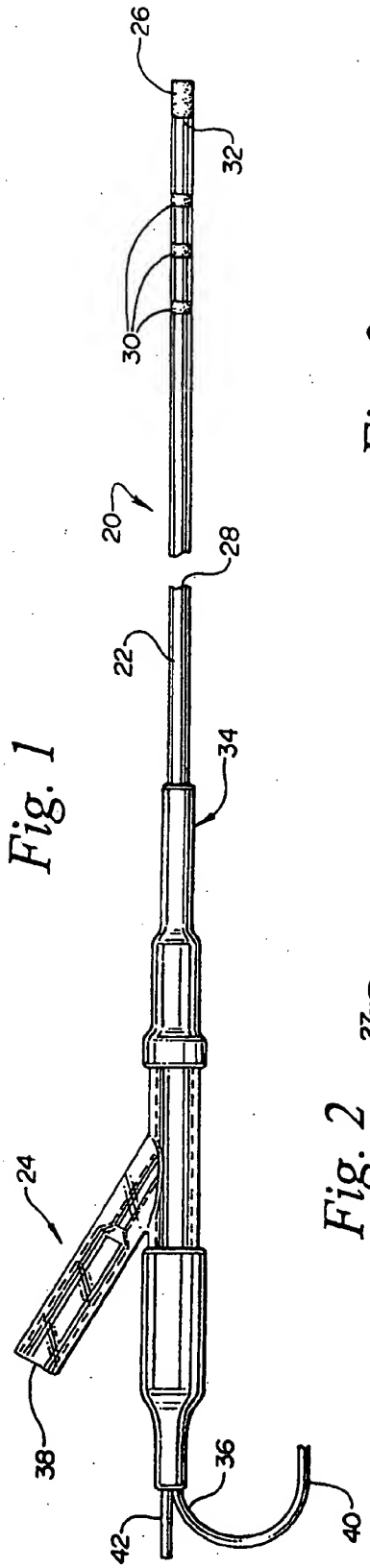


Fig. 1

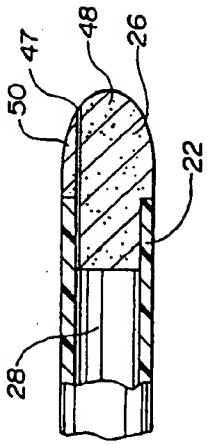


Fig. 3

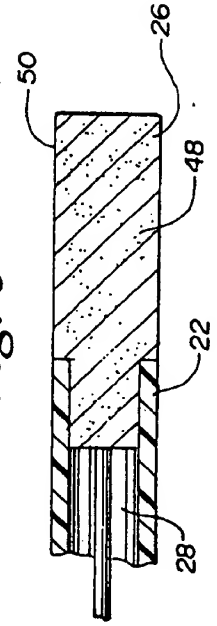


Fig. 5

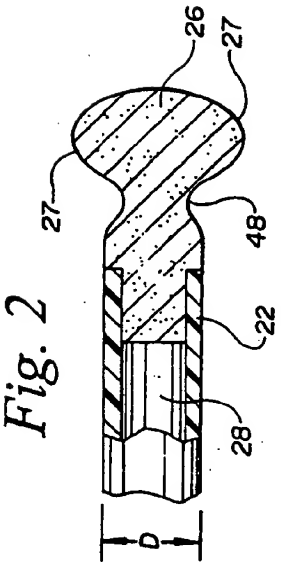


Fig. 2

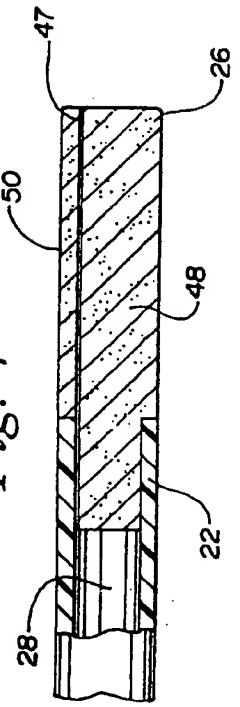


Fig. 4

Fig. 11

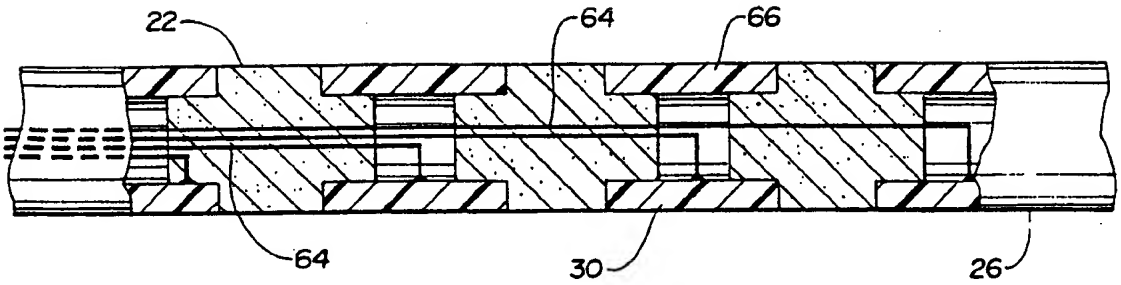


Fig. 6

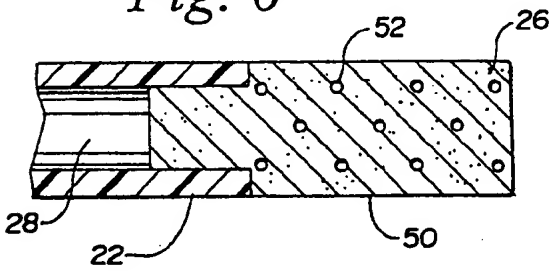


Fig. 7

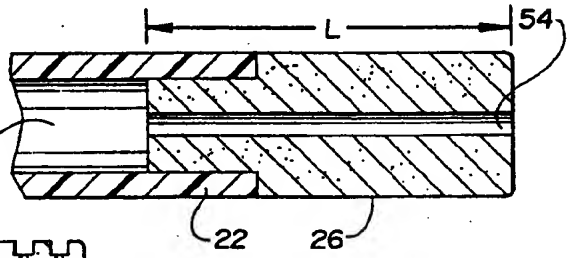


Fig. 9

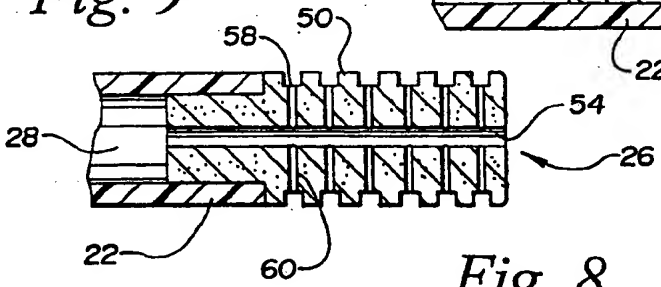


Fig. 8

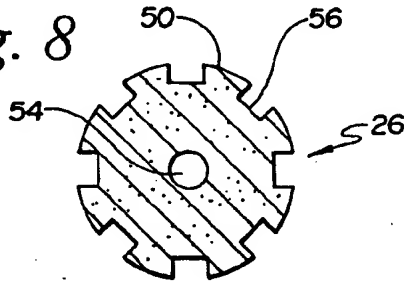


Fig. 10

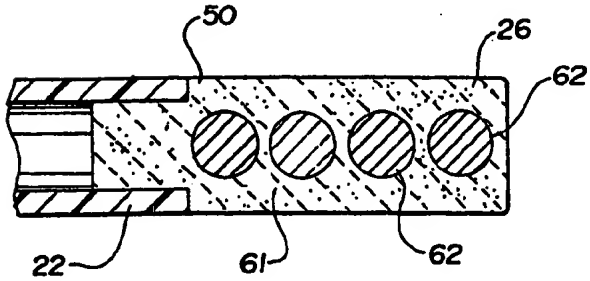


Fig. 12

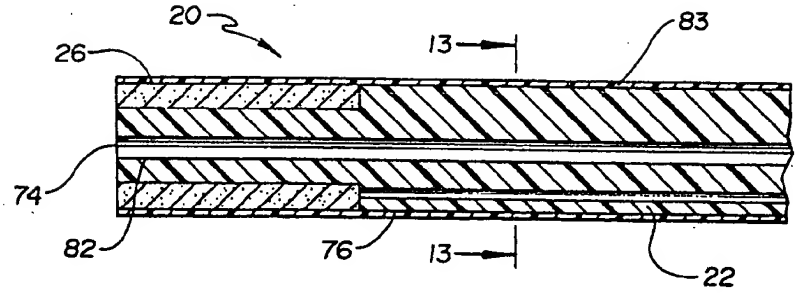


Fig. 13

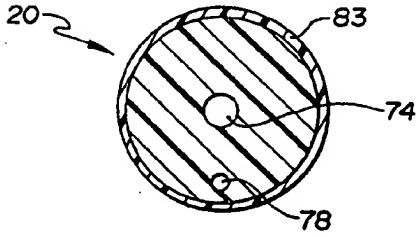


Fig. 14

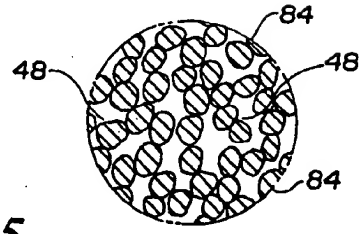


Fig. 15

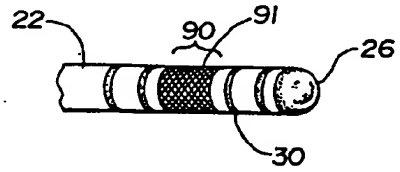
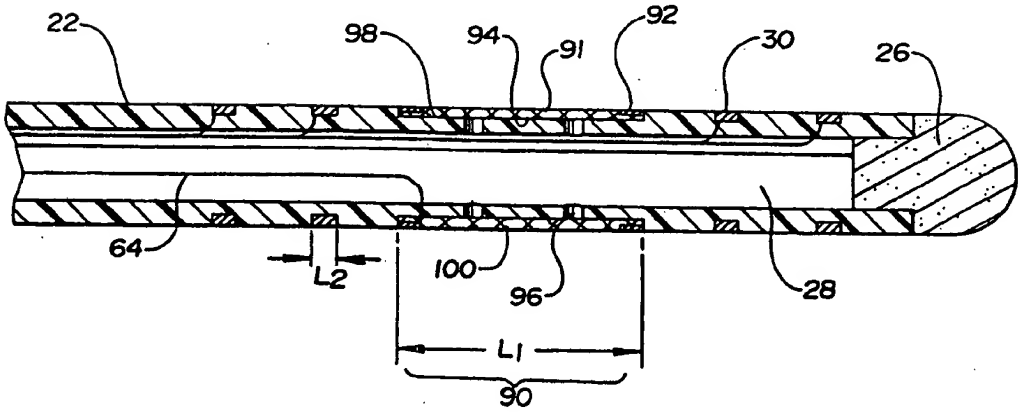


Fig. 16



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/14737

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :128/642; 604/20, 113; 607/102, 120, 122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/642; 604/20, 113; 607/102, 120, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US, A, 5,334,193 (NARDELLA) 02 August 1994.	1-8
Y	US, A, 4,506,680 (STOKES) 26 March 1985.	1-8
Y	US, A, 5,127,028 (DUTCHER ET AL.) 08 June 1993.	1-8
A	US, A, 5,242,441 (AVITALL) 07 September 1993.	3, 5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 27 MARCH 1995	Date of mailing of the international search report 10APR1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PERRY E. VAN OVER Telephone No. (703) 308-2911

Form PCT/ISA/210 (second sheet)(July 1992)*